DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MAY 10 2002

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R. Bruce Dickson
P. Susan Lively
Paul, Hastings, Janofsky & Walker LLP
1299 Pennsylvania Avenue, N.W.
Washington, D.C. 20004-2400

Re: Docket No. 01P-0122/CP1

Dear Mr. Dickson and Ms. Lively:

This letter answers your petition on behalf of Pharmacia Consumer Healthcare dated March 7, 2001, asking the Food and Drug Administration (FDA) to order Novartis Consumer Health (Novartis) to revise the labeling for its prescription motion sickness product Transderm Scop to remove false or misleading statements comparing Transderm Scop with oral dimenhydrinate (the active ingredient in Dramamine Original Formula). For the reasons that follow, the petition is granted.

The statement to which you object in the Transderm Scop labeling is that Transderm Scop "provided significantly greater protection [from motion-induced nausea and vomiting] than that obtained with oral dimenhydrinate." This statement appears in a section called "Clinical Results," that summarizes the results of clinical studies testing the effectiveness of Transderm Scop in reducing the incidence of motion-induced nausea and vomiting.

FDA evaluated this statement and determined that it is not supported by any data in Novartis' new drug application for Transderm Scop. The Agency requested that Novartis remove the statement from the Transderm Scop labeling. Novartis complied with FDA's request and submitted a labeling supplement to remove the sentence from its labeling. FDA approved that supplement on March 22, 2002. Accordingly, the petition is granted.

Sincerely yours,

Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research

01P-0122

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